

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-32 remain pending in the present application. It should be noted that no amendments have been made to the claims.

Applicant notes with appreciation the Examiner's indication that claim 6 would be allowed if rewritten in independent form. Applicant has not adopted the Examiner's suggestion at this time, because it is believed that the independent claim from which claim 6 depends is allowable for the reasons presented below.

Claims 1-6 and 7-32 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,041,780 to Richard et al. ("the '780 patent") in view of U.S. Patent No. 5,794,615 to Estes et al. ("the '615 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

Independent claim 1 recites determining an "average tidal volume of fluid received by such a patient from the volumes of fluid received by such a patient during the plurality of inspiratory phases". Claim 1 further recites that this "average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur." The average tidal volume is compared to a predetermined target tidal volume and the inspiratory positive airway pressure is adjusted based on the comparison.

The Examiner contends that the '780 patent teaches determining an average volume of fluid received by a patient from the volumes received by such a patient during the plurality of inspiratory phases and adjusting the IPAP level based on this comparison. Applicant respectfully notes that the '780 patent does not teach comparing an average *tidal* volume to a predetermined target volume. Instead, it teaches comparing a *minute* volume to a target minute volume. For example, column 5, lines 1-17, of the '780 patent explicitly states that the actual *minute* volume is compared to the adjusted *minute* volume. The inspiratory positive airway

pressure is then adjusted based on this comparison. The Examiner appears to be mixing apples and oranges in equating minute volume to tidal volume.

The Examiner admits that the '780 patent is silent with regards to the average volume being calculated irrespective of time. However, the Examiner takes the position that one skilled in the art would consider it obvious to modify the '780 patent so that it calculates an average volume that is not based on time. For this, the Examiner cites the '615 patent, which teaches detecting apneas and hypopneas by monitoring the peak flow or tidal volume over several breaths as compared to a longer term peak flow or tidal volume. According to the Examiner, one skilled in the art would use the tidal volume monitoring apnea detection technique taught by the '615 patent in the '780 patent because this would allow the system of the '780 patent to detect apneas and adjust the flow of fluid accordingly.

Applicant respectfully disagrees. The purpose of monitoring the minute volume in the '780 patent is to use it as the tool for determining when and how to change the inspiratory positive airway pressure of gas being delivered to the patient. According to the '780 patent, this pressure control technique is advantageous because it provides a very gradual IPAP adjustment so as not to arouse the patient from sleep. It also ensures that adequate ventilation is provided to the patient. See column 3, lines 20-25, and column 5, lines 18-20, of the '780 patent. Applicant respectfully submits that one skilled in the art would not consider it obvious to use an average volume that is calculated irrespective of time in the '780 patent because doing so represents a complete departure from the "minute volume" technique used on the '780 patent and may compromise the advantages espoused in the '780 patent. If the proposed combination of reference makes a prior art reference inoperable for its intended purpose, the resulting inoperable prior art reference may be considered to teach away from the proposed combination, i.e., not teach the combination, thereby supporting a showing of nonobviousness. *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). It is well settled that obviousness cannot be established if the proposed modification to the reference renders it useless for its intended purpose. *Ex parte Westphalen*, 159 U.S.P.Q. 507, 508 (Bd. App. 1967); *see also, Ex parte Hartmann*, 186 U.S.P.Q. 366, 367 (Bd. App. 1974).

Minute volume is calculated by multiplying the patient's tidal volume (or average tidal volume) by the breath rate, which is also referred to as the breathing frequency. See, e.g., column 3, lines 3-7, column 4, lines 17-21, and column 4, lines 65, through column 5, line 1, of the '780 patent. The Examiner's suggested modification requires ignoring the breathing frequency entirely in determining the volume to be provided to the patient by the system taught in the '780 patent. One skilled in the art recognizes is not a trivial modification and changes the fundamental basis for the pressure support control taught by the '780 patent.

Applicant respectfully submits that the one skilled in the art would not need to use the non-time-based "average volume" apnea/hypopnea detection technique taught by the '615 patent in the system taught by the '780 patent, because the system taught by the '780 patent allegedly provides an adequate technique for dealing with apneas and hypopneas, i.e., by monitoring the minute volume. Why would one skilled in the art replace one system that allegedly works, with another system that may not provide the advantages of ensuring adequate ventilation touted by the '780 patent? Applicant submits that one skilled in the art would not make such a modification. Thus, the Examiner's proposed suggestion as to why these references would be combined lacks merit.

The fact that it was known to use tidal volumes as a means for detecting apneas and hypopnea does not provide any suggestion as to why or how this detection technique should be incorporated into the teachings of the '780 patent absent the teachings of the present invention. Of course, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The Federal Circuit Court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciated the claimed invention." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992)(quoting *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)).

For the reasons presented above, applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. Independent claims 7, 13, 19, 23, and 27 are likewise patentable over the cited references, because they include language regarding the

"average volume" corresponding to that of claim 1. In addition, claims 2-5, 8-12, 14-18, 20-22, 24-26, and 28-32 are also not rendered obvious due to their dependency from one of the above-noted independent claims. Accordingly, applicant respectfully request that the above rejection of claims 1-5 and 7-32 be withdrawn.

This response is being filed within the three-month statutory response period which expires on January 7, 2004. In addition, no additional claim fees are believed to be required as the claims have not been amended. Nevertheless, the Commission is authorized to charge the any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

By Michael W. Haas

Michael W. Haas

Reg. No.: 35,174

Tel. No.: (724) 387-5026

Fax No.: (724) 387-5021

RESPIRONICS, INC.
1010 Murry Ridge Lane
Murrysville, PA 15668-8525